DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 10, 2015

Breast-Med Incorporated
Dr. Michael Nelson
President
1745 Bridgewater Road
Golden Valley, MN 55422

Re: K133697
Trade/Device Name: Breast-Med Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: April 6, 2015
Received: April 8, 2015

Dear Dr. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133697

Device Name
Breast-Med Tissue Marker

Indications for Use *(Describe)*
The Breast-Med Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY – K133697

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Breast-Med Tissue Marker is provided below.

Submitted by:	Breast-Med, Inc.
Contact Person:	Michael Nelson, M.D. President Breast-Med, Inc. 1745 Bridgewater Road Golden Valley, MN 55422 Tel: 763-522-2121 Email: mtnelson@comcast.net
Date of Summary:	April 10, 2015
Device Trade Name:	Breast-Med Tissue Marker
510(k) Number:	K133697
Product Code:	NEU
Common or Usual Name:	Tissue Marker
Classification Name:	Implantable clip (21 CFR 878.4300)
Predicate Device(s):	BiomarC Tissue Marker, K032347 KDM-Mark1 Tissue Marker, K093473
Device Description:	The Breast-Med Tissue Marker is a sterile, nonpyrogenic, single use tissue marker consisting of a polymeric tube filled with a dessicated solution of sodium chloride with trace amounts of gadolinium chelate that is visible on standard radiographs (x-ray, mammography) as well as ultrasound and Magnetic Resonance Imaging (MRI). The tissue marker is placed into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location.
Indication for Use:	The Breast-Med Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

Technological Characteristics:

The technological characteristics of the Breast-Med Tissue Marker are substantially equivalent to those of the predicates in terms of the following:

- Intended use
- Indications for use
- Target population
- Fundamental scientific technology
- Patient-contacting materials
- Method of delivery

Performance Testing Summary:

Bench testing was performed to verify that the subject device has equivalent radiographic visualization to the predicates under standard radiographs, ultrasound, and MRI in both tissue and phantom models.

Safety testing of the device was performed utilizing the following standards: ASTM F2182, ASTM F2052, ASTM F2213 and ASTMF2119.

Conclusion:

The Breast-Med Tissue Marker is substantially equivalent to the named predicates based on technological comparison, indications for use, and laboratory and other safety testing. It is concluded that there are no new questions of safety and effectiveness.